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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,059	09/23/2003	Victor Schoenle	10527-477001	2738

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FISH & RICHARDSON PC
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
AUGHENBAUGH, WALTER	
ART UNIT	PAPER NUMBER
1794	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/669,059	SCHOENLE ET AL.	
	Examiner	Art Unit	
	WALTER B. AUGHENBAUGH	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *74,77-84,87-91,130-133 and 140-143* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *74,77-84,87-91,130-133 and 140-143* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement of Applicant's Amendments

1. The amendments made in claims 74, 80, 84 and 89 in the Amendment filed March 11, 2008 (Amdt. C) have been received and considered by Examiner.

2. New claims 140-143 presented in Amdt. C have been received and considered by Examiner.

Claim Rejections - 35 USC § 102

3. Claims 74, 77, 78, 80-82, 140 and 141 are rejected under 35 U.S.C. 102(b) as being anticipated by Pinchuk et al. (USPN 6,110,142).

In regard to claim 74, Pinchuk et al. teach a component (catheter, item 21, which includes balloon, item 26, Fig. 1, col. 5, lines 14-16 and col. 1, lines 24-27 and 33-36, which is tube-shaped), where the component comprises a polyamide having a tensile strength of between about 20,000 and about 32,000 psi (col. 11, lines 17-21), a range that overlaps with the claimed tensile strength values of at least about 21,000 psi. Pinchuk et al. teach that the component has a thickness of 0.0002-0.002 inches (col. 13, lines 20-31), a range that overlaps with the claimed range. The recitation "of a catheter shaft" has been given little patentable weight since the present claim language does not structurally distinguish the claimed invention from that which is taught by the prior art.

In regard to claim 80, Pinchuk et al. teach a tube-shaped portion (balloon, items 33 and 34, Fig. 1, col. 5, lines 6-9) of a catheter (item 21, Fig. 1, col. 5, lines 14-16) where the tube-shaped portion comprises a polyamide having a tensile strength of between about 20,000 and about 32,000 psi (col. 11, lines 17-21), a range that overlaps with the claimed tensile strength

values of at least about 21,000 psi. Pinchuk et al. teach that the component has a thickness of 0.0002-0.002 inches (col. 13, lines 20-31), a range that overlaps with the claimed range. The recitation "of a catheter shaft" has been given little patentable weight since the present claim language does not structurally distinguish the claimed invention from that which is taught by the prior art.

In regard to claims 77 and 81, Pinchuk et al. teach that the balloon can be coated with lubricants such as polyvinyl pyrrolidone (col. 11, lines 6-9) and therefore teach that the balloon comprises a first layer (the polyamide layer of Pinchuk et al.) and a second layer (the polyvinyl pyrrolidone coating layer of Pinchuk et al.) where the first layer has a different flexibility from the second layer (since the two layers consist of different materials, the two layer necessarily have different flexibilities).

In regard to claims 78 and 82, Pinchuk et al. teach that the tensile strength is between about 20,000 and about 32,000 psi (col. 11, lines 17-21), a range that overlaps with the claimed tensile strength values of at least about 22,500 psi.

In regard to claims 140 and 141, Pinchuk et al. teach that the component has a thickness of 0.0002-0.002 inches (col. 13, lines 20-31), a range that overlaps with the claimed range.

4. Claims 84, 88, 89, 91, 132, 133, 142 and 143 are rejected under 35 U.S.C. 102(b) as being anticipated by Burgmeier (USPN 6,200,290).

In regard to claims 84 and 88, Burgmeier teaches a component of a catheter device (col. 1, lines 10-31 and lines 43-45, col. 1, line 52-col. 2, line 34 and col. 3, lines 17-64), where the component includes a region that comprises a polyamide (for example, PEBAX 6333) having a

hoop stress of (for example) 24,112 psi (Table I, col. 5 and 6, Balloon No. 1), where the region of the component is tube-shaped (Fig. 1) (see rest of document for more embodiments comprising a polyamide each having a hoop stress that is greater than 3300 psi). Burgmeier teaches that the component has a thickness of 0.00125 inches and 0.0013 inches at different locations along the component (Table I, col. 5 and 6, Balloon No. 1), amounts that fall within the claimed range. The recitation "of a catheter shaft" has been given little patentable weight since the present claim language does not structurally distinguish the claimed invention from that which is taught by the prior art.

In regard to claims 89 and 91, Burgmeier et al. teaches a tube-shaped portion of a catheter where the tube-shaped portion includes a region (col. 1, lines 10-31 and lines 43-45, col. 1, line 52-col. 2, line 34 and col. 3, lines 17-64) that comprises a polyamide (for example, PEBAX 6333) having a hoop stress of (for example) 24,112 psi (Table I, col. 5 and 6, Balloon No. 1) (see rest of document for more embodiments comprising a polyamide each having a hoop stress that is greater than 3300 psi). Burgmeier teaches that the component has a thickness of 0.00125 inches and 0.0013 inches at different locations along the component (Table I, col. 5 and 6, Balloon No. 1), amounts that fall within the claimed range. The recitation "of a catheter shaft" has been given little patentable weight since the present claim language does not structurally distinguish the claimed invention from that which is taught by the prior art.

In regard to claims 132 and 133, all PEBAX polyamides, including (for example, PEBAX 6333) is a copolymer.

In regard to claims 142 and 143, Burgmeier teaches that the component has a thickness of 0.00125 inches and 0.0013 inches at different locations along the component (Table I, col. 5 and 6, Balloon No. 1), amounts that fall within the claimed range.

Claim Rejections - 35 USC § 103

5. Claims 79 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchuk et al. (USPN 6,110,142) in view of Burgmeier (USPN 6,200,290).

Pinchuk et al. teach the component and tube-shaped portion of a catheter as discussed in regard to claims 74 and 80 in the previous Office Action. Pinchuk et al. teach that the polymer of the balloon is a polyamide (col. 11, lines 17-21).

Pinchuk et al. fail to teach that the balloon has a hoop stress of at least about 3300 psi.

Burgmeier teaches a balloon (col. 1, lines 10-31 and lines 43-45, col. 1, line 52-col. 2, line 34 and col. 3, lines 17-64) that includes a region that comprises a polyamide (for example, PEBAX 6333) having a hoop stress of (for example) 24,112 psi (Table I, col. 5 and 6, Balloon No. 1). Therefore, one of ordinary skill in the art would have recognized to have used the material comprising a polyamide that has a hoop stress of (for example) 24,112 psi taught by Burgmeier as the polyamide of the balloon of Pinchuk et al. since a polyamide that has a hoop stress of 24,112 psi (and similar values [see rest of document for more embodiments comprising a polyamide]) is a well known suitable material for use as the material of a catheter balloon as taught by Burgmeier.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the material comprising a polyamide that has a hoop stress of (for example) 24,112 psi taught by Burgmeier as the polyamide of the balloon of Pinchuk et al. since

a polyamide that has a hoop stress of 24,112 psi (and similar values [see rest of document for more embodiments comprising a polyamide]) is a well known suitable material for use as the material of a catheter balloon as taught by Burgmeier.

6. Claims 87 and 90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burgmeier (USPN 6,200,290) in view of Pinchuk et al. (USPN 6,110,142).

In regard to claim 87, Burgmeier teaches the component as discussed above.

Burgmeier fails to teach that the component comprises a first layer and a second layer where the first layer has a different flexibility from that of the second layer.

Pinchuk et al., however, teach that balloons can be coated with non-thrombogenic lubricants such as polyvinyl pyrrolidone (col. 11, lines 6-9) and therefore teach that balloons can comprise a first layer (the polyamide layer) and a second layer (the polyvinyl pyrrolidone coating layer of Pinchuk et al.) where the first layer has a different flexibility from the second layer (since the two layers consist of different materials, the two layers necessarily have different flexibilities). Therefore, one of ordinary skill in the art would have recognized to have coated the component of Burgmeier with a non-thrombogenic lubricant such as polyvinyl pyrrolidone since it is well known to coat balloons with non-thrombogenic lubricants in order to increase the lubricity of the balloons as taught by Pinchuk et al.

In regard to claim 90, Burgmeier teaches the tube shaped portion as discussed above.

Burgmeier fails to teach that the tube shaped portion comprises a first layer and a second layer where the first layer has a different flexibility from that of the second layer.

Pinchuk et al., however, teach that balloons can be coated with non-thrombogenic lubricants such as polyvinyl pyrrolidone (col. 11, lines 6-9) and therefore teach that balloons can comprise a first layer (the polyamide layer) and a second layer (the polyvinyl pyrrolidone coating layer of Pinchuk et al.) where the first layer has a different flexibility from the second layer (since the two layers consist of different materials, the two layers necessarily have different flexibilities). Therefore, one of ordinary skill in the art would have recognized to have coated the tube shaped portion of Burgmeier with a non-thrombogenic lubricant such as polyvinyl pyrrolidone since it is well known to coat balloons with non-thrombogenic lubricants in order to increase the lubricity of the balloons as taught by Pinchuk et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have coated the tube shaped portion of Burgmeier with a non-thrombogenic lubricant such as polyvinyl pyrrolidone since it is well known to coat balloons with non-thrombogenic lubricants in order to increase the lubricity of the balloons as taught by Pinchuk et al.

7. Claims 130 and 131 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchuk et al. (USPN 6,110,142) in view of Wang et al. (USPN 6,124,007).

Pinchuk et al. teach the component and tube-shaped portion of a catheter as discussed above. Pinchuk et al. teach that the polymer of the balloon is a polyamide (col. 11, lines 17-21). Pinchuk et al. fails to specifically teach a polyamide copolymer. PEBAX (polyether block amide) is listed in some of the titles of the publications listed in the "Other Publications" section of Pinchuk et al.

Wang et al. disclose that copolymers of polyamides such as polyether block amide are suitable material for use as a material of an angioplasty balloon (col. 4, line 33-col. 5, line 67).

Therefore, one of ordinary skill in the art would have recognized to have used polyether block amide copolymer as a material of the balloon of Pinchuk et al. since a polyether block amide copolymer disclosed by Wang et al. is a well known suitable polyamide material for use in making angioplasty balloons as taught by Wang et al.

Response to Arguments

8. Applicant's arguments regarding the 35 U.S.C. 102 rejection of claims 74 and 80 as being anticipated by Pinchuk et al. have been fully considered but are not persuasive.

Pinchuk et al. teach that the component has a thickness of 0.0002-0.002 inches (col. 13, lines 20-31), a range that overlaps with the claimed range. The recitation "of a catheter shaft" has been given little patentable weight since the present claim language does not structurally distinguish the claimed invention from that which is taught by the prior art.

9. Applicant's arguments regarding the 35 U.S.C. 102 rejection of claims 84 and 89 as being anticipated by Burgmeier have been fully considered but are not persuasive.

Burgmeier teaches that the component has a thickness of 0.00125 inches and 0.0013 inches at different locations along the component (Table I, col. 5 and 6, Balloon No. 1), amounts that fall within the claimed range. The recitation "of a catheter shaft" has been given little patentable weight since the present claim language does not structurally distinguish the claimed invention from that which is taught by the prior art.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B. Aughenbaugh whose telephone number is (571) 272-1488. While the examiner sets his work schedule under the Increased Flexitime Policy, he can normally be reached on Monday-Friday from 8:45am to 5:15pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye, can be reached on (571) 272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Walter B Aughenbaugh /
Examiner, Art Unit 1794

6/05/08

/Rena L. Dye/
Supervisory Patent Examiner, Art Unit 1794